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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/646,595 | 08/22/2003 | Stanley W. Huth | 14628/301681 | 9800 |

33357 7590 05/19/2006

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| EXAMINER |
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MARTIN, PAUL C

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| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/646,595 | Applicant(s) HUTH ET AL. | |
| | Examiner Paul C. Martin | Art Unit 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 11-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 and 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/14/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-10 are pending in this application.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-10) in the reply filed on 04/20/06 is acknowledged. Claims 11-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/20/06.

Claims 1-10 were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the probe molecule eosin Y, the antimicrobial PHMB and preservative Benzalkonium chloride (BC), and visible light spectrophotometry, does not reasonably provide enablement for all possible dyes or probes, antimicrobials and preservatives, or sources of light radiation and detection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988).

In re Wands stated that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The instant specification only provides working examples drawn to analyzing one species of antimicrobial and preservative using one dye probe and one means of detection. It is unreasonable to expect that the ordinary artisan would then be able to extrapolate this technique to encompass the use of any dye, with any form of antimicrobial or preservative, using any means of producing light and detection. One of ordinary skill would be subjected to an undue amount of experimentation in order to perform the claimed invention as no guidance is provided or suggested as to how to apply the invention to such disparate dyes as coumarin or Cy5, using laser fluorescent microscopy or infrared spectroscopy, and analyzing biological antimicrobials such as antibodies. The state of the art relating to the Biological Sciences is, at best, unpredictable in terms of how new combinations of experimental components will interact and a large degree of experimentation is expected.

Though the level of skill in the art is high, given the extreme breadth of the claims the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kovacs-Hadady *et al.* (1998).

Kovacs-Hadady teaches a cell-free system for determining the presence of the preservative/antimicrobial Benzalkonium Chloride (BC), wherein the probe Eosin-Y (a dye molecule) is used to detect the presence of BC based on absorbance readings from a light spectroscope (Pg. 735, Column 1, Lines 35-40 and Column 2, Lines 1-17 and Fig. 1).

Although Kovacs-Hadady did not explicitly teach a method for predicting the antimicrobial activity of an agent, the interaction between the BC and the eosin is inherently analogous to the interaction which would occur between the BC and a microbial cell membrane, since BC is known in the art to disrupt or destroy microbial cell membranes upon contact.

The MPEP states: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Kovacs-Hadady teaches the use of a calibration graph of absorbencies wherein the activity of the eosin-BC interaction can be analyzed in Fig. 1a, wherein the activity of the interaction between eosin-BC was plotted and adjusted for blank/control absorbance.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure :

Vehige *et al.* "Cytoprotective Properties of Carboxymethyl Cellulose (CMC) When Used Prior to Wearing Contact Lenses Treated With Cationic Disinfecting Agents"; *Eye and Contact Lens*, Vol. 29, No. 3 (2003) pp. 177-180.

Richards *et al.* "Electron microscope study of effect of Benzalkonium Chloride and edetate disodium on cell envelope of *Pseudomonas aeruginosa*"; *Journal of Pharmaceutical Science*, Vol. 65, No. 1 (1976) pp. 76-80 (abstract only).

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

05/04/06

Patricia J. Fite
Primary 1655